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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,746	07/26/2001	Yajun Guo		1834

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OXCOMAX ACQUISITION CORP  
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EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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02/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/915,746	<b>Applicant(s)</b> GUO ET AL.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,6 and 8-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,6,8-13 and 18 is/are rejected.
- 7) ☒ Claim(s) 14-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

After review and reconsideration, the finality of the Office action of July 31, 2007 is withdrawn.

The amendment filed January 23, 2008 has been entered.

Claims 1, 4 and 7 have been canceled. claims 2, 3 and 8 have been amended. Claims 2, 3, 5, 6, 8-18 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5, 6, 8, 9, 11, 12 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11, cited in a previous Office action) .

The specification states that the SM5-1 antibody was deposited under the Accession number HB-12588 (page 4, lines 10-11)..

The abstract of Chen et al discloses that the SM5-1 antibody which binds to human fibronectin. The abstract did not specifically disclose that the antibody was conjugated to a label which produces a detectable signal, however this would be inherent in the immunohistochemical analysis of the tissue samples. The abstract discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and detecting the formation of immune complexes as indicative of melanoma.

Applicant has previously argued (in the remarks filed December 29, 2004) that the instant antibody is different from the antibody of the abstract of Chen in that the instant antibody does

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not bind to a fibronectin. Applicant has previously presented the Declaration of Dr. Guo which demonstrated that "fibronectin" does not compete with the binding of antibody SM5-1, and an anti-fibronectin antibody does not bind to the same antigen as the antibody SM5-1. This has been re-considered but not found persuasive. It is well known in the art that fibronectin exists as many alternatively spliced isomers. Trefzer et al, (BMC Cancer, 2006, vol. 6, pp. 1-12) includes one of the instant inventors as an author and teaches that the SM5-1 antibody recognizes a fibronectin variant, widely expressed in melanoma (page 10, under "conclusion", see page 9, second column, first full paragraph for fibronectin isoforms). Thus, given that the SM5-1 antibody binds to an antigenic site on a novel splice-variant of fibronectin present on melanoma cells, it would not be expected that a generic "fibronectin" would compete with the binding of the SM5-1 antibody due to the absence of the particular antigenic site present on the novel splice site variant. The Declaration of Dr. Guo further states that an antibody known to bind to all fibronectin protein was effectively blocked by fibronectin. This is also not persuasive, for the reasons above. namely that if the SM5-1 antibody bound to a novel fibronectin isoform, competition experiments using fibronectins lacking said isoform would not result in competition for the SM5-1 antibody. The Declaration of Dr. Guo states that the generic anti-fibronectin antibody bound to proteins of molecular weight 250kDa and 200kDa in Hk-2 cells versus the SM5-1 antibody of Chen which did not bind any protein in HK-2 cells. This has been considered and not found persuasive for the reason set forth above, regarding the specific antigen to which SM5-1 binds and the lack thereof in a generic fibronectin preparation. which lacks the specific antigenic site to which the SM5-1 antibody binds.

Applicant has previously argues that the Chen reference is not enabling because without the antibody in hand one of skill in the art would not know how to identify antibodies with the same binding characteristics. This has been considered but not found persuasive. The examiner maintains that the antibody disclosed by Chen is the same as the instant antibody. 35 U.S.C. 102(b) states that the description of the invention in a printed publication more than one year prior to the application for a patent is a statutory bar.

Claims 2, 3, 5, 6, 8-13 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Trefzer et al (Journal of Dermatological Science, March 1998, Vol. 16, suppl. 1, page S110, reference 57 of the IDS submitted October 4, 2002, cited in a previous Office action).

Claim 10 embodies the method of claim 9 wherein the tissue sample is paraffin-embedded or cryo-preserved.

The abstract of Trefzer et al discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and detecting the formation of immune complexes as indicative of melanoma. The abstract discloses that the SM5-1 detected melanoma in paraffin-embedded melanocytic tissues by means of the APAAP-technique for staining the tissues, thus fulfilling the specific embodiment of claim 9, drawn to a detectable label, claim 10, drawn to a paraffin-embedded tissue and claim 13 drawn to an enzyme as a detectable label.

Applicant has not previously argued that the antibody of Trefzer is different from the instant antibody. Applicant has previously argues that the disclosure of Trefzer is insufficient enablement without the deposited antibody. This has been considered but not found persuasive. 35 U.S.C. 102(a) states that the description of the invention in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, prohibits the entitlement of the applicant from obtaining a patent.

Claims 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643